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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,062	07/30/2001	Donald J. Schremp	10004377-1	2666

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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER	
CHIN, CHRISTOPHER L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,062	SCHREMP, DONALD J.	
	Examiner	Art Unit	
	Christopher L. Chin	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,12,17,18,20-24 and 71-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12,17,18,20-22,24,71-77,79-84,86-93 and 95-98* is/are rejected.

7)☒ Claim(s) *23,78,85 and 94* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 71-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 71 is vague. It is suggested that applicants insert the word --horizontally-- in line 6, after "ledge" to clarify the spatial relationship between the ledge and bottom edge of the said at least one wall of the housing. For example, looking at Figure 3, the ledge (57) extends horizontally away from the top edge (56) well (54).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 5, 12, 20, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Lennon et al.

Lennon et al (US Patent 4,999,163) discloses a device for conducting immunoassays. As shown in Figure 2, the device has a housing (12) with a lid element (30). The interior of the housing (12) underneath lid element (30) is considered a well. Assay element (18) is considered a support and resides in the well. Immunoassay

reagents, such as antibodies (i.e. biopolymers), can be immobilized in assay element (18) (col. 7, lines 20-35, and col. 8, lines 20-26). A foil cover (46) is attached to lid element (30).

The bottom portion of lid element (30) comprises a vertical wall region (34) that flares open into a frustoconical segment (38). Vertical wall region (34) and frustoconical segment (38) is considered to read on the structural arrangement in the last 2 lines of claim 1.

4. Claims 71, 72, 73, 76, 79, 81, 82, 83, and 89-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al.

Chen et al (US Patent 5,096,809) discloses a device for performing assays to detect an analyte. A representative assay device (10) having a porous analytical field is shown in Figure 1. The assay device (10) has a rectangular housing (12) which has a top (14) and a bottom (16). When assembled, a space (20) is defined inside the assay device. The housing (12) has openings (24) (i.e. wells) that permit communication between the outside of the housing (12) and the inside (20) of housing (12). Looking at Figure 2, a ledge extends horizontally away from the top edge of each well (24) to a wall of the housing that slopes upward. A porous support (32) lies underneath and considered to be in each of the wells (24). Porous support (32) is a porous membrane to which reagents for the analysis of interest may be fixed either by chemical binding or physical impregnation. The analyte specific reagent may be a member of a ligand-antiligand pair, including antibodies and RNA or DNA sequences (cols. 3-4).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3, 4, 17, 18, 22, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennon et al.

See above for the teachings of Lennon et al.

Lennon et al differs from the instant invention in failing to teach the specific dimensions recited in claim 3 for the assay element (18) or the specific dimensions and angles recited in claims 4, 17, 18, and 98.

However, the optimum dimensions and angles required for each of the components in the assay device of Lennon et al for optimum assay results can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art.

7. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lennon et al in view of Chen et al.

See above for the teachings of Lennon et al.

The device of Lennon et al differs from the instant invention in failing to teach the use of polynucleotides as an analyte detection reagent in assay element (18).

See above for the teachings of Chen et al.

It would have been obvious to one of ordinary skill in the art to use polynucleotides, such as RNA or DNA, as taught by Chen et al in the assay element (18) of Lennon et al because Lennon et al is generic with respect to what assay reagents may be incorporated into assay element (18) and Chen et al shows that it is conventional in the art to use polynucleotide reagents in assay elements such as those disclosed in Lennon et al. Furthermore, the choice of analyte to be detected dictates the appropriate reagents to be used. For the detection of analyte polynucleotides, one of ordinary skill in the art would use the appropriate reagent, such as complementary polynucleotide sequences.

8. Claims 74, 75, 77, 80, 84, 86, 87, 88, 96, and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al.

See above for the teachings of Chen et al.

The device of Chen et al differs from the instant invention in failing to teach the dimensions recited in claim 97 for the porous support (32) or the specific dimensions and angles recited in claims 74, 75, 77, 87, 88, and 96. The device of Chen et al further differs from the instant invention in the shape and thus number of walls forming the sample receiving region in Figure 2 of Chen et al as set forth in claims 80, 84, and 86.

However, the optimum dimensions and angles required for each of the components in the assay device of Chen et al for optimum assay results can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art.

With respect to claims 80, 84, and 86, since the criticality of the shape of the ledge and opening above the ledge and the number of walls forming the opening above the ledge set forth in claims 80, 84, and 86 has not been established, the optimum shape of the ledge and opening above the ledge and the number of walls forming the opening above the ledge in the sample receiving region in Figure 2 of Chen et al can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art.

9. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al in view of Lennon et al.

See above for the teachings of Chen et al.

The device of Chen et al differs from the instant invention in failing to teach the use of a cover over the wells (24).

See above for the teachings of Lennon et al, specifically the removable foil cover (46).

It would have been obvious to one of ordinary skill in the art to incorporate a removable foil cover, as taught by Lennon et al, into the device of Chen et al to cover the sample receiving region because such a cover provides the advantages of

protecting the sample receiving region from contamination and being removable when the device of Chen et al is to be used.

Allowable Subject Matter

10. Claims 23, 78, 85, and 94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher L. Chin
Primary Examiner
Art Unit 1641

5/16/05